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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,007	11/28/2000	James L. Kurk	1416.30US01	7252

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EXAMINER

STAICOVICI, STEFAN

ART UNIT	PAPER NUMBER
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1732

DATE MAILED: 12/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/724,007

Applicant(s)

KURK ET AL.

Examiner

Stefan Staicovici

Art Unit

1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 29-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-11 and 29-37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment filed September 18, 2002 (Paper No. 8) has been entered. No claims have been amended. Claims 12-28 have been canceled. New claims 30-37 have been added. Claims 1-11 and 29-37 are pending in the instant application.

Election/Restrictions

2. Applicant's election of Group I in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 36, it is unclear how a "sharp edge" can have a "radius of curvature." Further clarification is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1732

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 5-7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Jansen *et al.* (US Patent No. 5,376,113) or NL 1008349.

Jansen *et al.* ('113) teach the claimed mandrel for making a heart valve (valve prostheses), said mandrel (7) having a plurality of ridges containing therebetween contoured surfaces (5) for forming polymer leaflets of said heart valve (valve prostheses) and further including an edge separating a top flat surface (8) from said contoured surfaces (5), said edge corresponding to free edges of said heart valve (valve prostheses) (see Figure 1).

Regarding claim 2, Jansen *et al.* ('113) teach a mandrel (7) having three contoured surfaces (5) defined by three ridges and three scallop regions (6).

In regard to claims 5 and 6, Figure 1 of Jansen *et al.* ('113) teach that the angle between the top surface (8) and the contoured surfaces (5) is no larger than 90 degrees.

Specifically regarding claim 7, Jansen *et al.* ('113) teach a flat top surface (8).

Regarding claim 10, Jansen *et al.* ('113) teach that contoured surfaces (5) are on the outside of mandrel (7).

7. Claims 1-2, 5-7, 10 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by NL 1008349.

NL 1008349 teaches the claimed mandrel for making a heart valve (valve prostheses), said mandrel having a plurality of ridges containing therebetween contoured surfaces for forming polymer leaflets of said heart valve (valve prostheses) and further including an edge separating a

Art Unit: 1732

top surface from said contoured surfaces, said edge corresponding to free edges of said heart valve (valve prostheses) (see Figure 8A).

Regarding claim 2, NL 1008349 teaches a mandrel having three contoured surfaces defined by three ridges and three scallop regions.

In regard to claims 5 and 6, Figure 8A of NL 1008349 teaches that the angle between the top surface (8) and the contoured surfaces (5) is no larger than 90 degrees.

Specifically regarding claim 7, NL 1008349 teaches a flat top surface (8).

Regarding claim 10, NL 1008349 teaches that contoured surfaces (5) are on the outside of mandrel.

In regard to claim 30, NL 1008349 teaches a slightly concave surface.

8. Claims 1, 8, 11, 29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by *Pierce et al.* (US Patent No. 4,364,127).

Pierce et al. ('127) teach the claimed mandrel for making a heart valve (valve prostheses), said mandrel (32) having a plurality of ridges extending between contoured surfaces which form scallop regions (30) of said heart valve (14) (see Figures 1 and 6). Further, *Pierce et al.* ('127) teach a top surface (40) formed by shims (35) that define an edge separating the contoured surfaces (see Figures 10 and 11).

Regarding claim 8, *Pierce et al.* ('127) teach a top surface having both flat and curved portions (see Figures 1 and 9).

Regarding claim 11, *Pierce et al.* ('127) teach contoured surfaces on the inside of mandrel (32) (see Figures 1 and 6).

Art Unit: 1732

In regard to claim 29, Pierce *et al.* ('127) teach a closed configuration of the resulting heart valve such that contoured surfaces of adjacent leaflets form a common boundary (see Figure 11).

Specifically regarding claim 31, Pierce *et al.* ('127) teach a convex surface.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 3-4, 9 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen *et al.* (US Patent No. 5,376,113) or NL 1008349 in view of Moe *et al.* (US Patent No. 6,174,331 B1) and Stockum (US Patent No. 4,135,867).

Jansen *et al.* ('113) or NL 1008349 teaches the basic claimed mandrel as described above.

Regarding claims 3-4 and 34, Jansen *et al.* ('113) or NL 1008349 do not teach a dip molding mandrel having a curved edge (radius of curvature). Moe *et al.* ('331) teach a heart valve obtained by dip molding, said heart valve having polymer leaflets which exhibit a radius of curvature and an increased thickness at the edge (see col. 3, lines 50-60; col. 6, lines 31-51 and Figure 6A). Further, it should be noted that it is well known that in a dip molding process, as evidenced by Stockum ('867), a radius of curvature on the mandrel provides for improved releasability of the molded article (see Abstract). It should be noted that upon Applicants'

Art Unit: 1732

request, the teachings of Stockum ('867) were employed to show that it is well known that in a dip molding process a radius of curvature on the mandrel provides for improved releasability of the molded article

Furthermore, it is submitted that a dip mold used to make such a configuration includes a radius of curvature in order to increase the thickness of the edge, hence it is submitted that the dip mold (mandrel) of Moe *et al.* ('331) includes an edge having a radius of curvature. Furthermore, it is submitted that the actual radius of curvature is a result-effective variable. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Therefore, it would have been obvious for one of ordinary skill in the art to have used routine experimentation to determine an optimum radius of curvature in the mandrel of Jansen *et al.* ('113) or NL 1008349 in view of Moe *et al.* ('331) and Stockum ('867), because Moe *et al.* ('331) specifically teach that a thicker leaflet edge provides for an improved heart valve due to an increased strength to compressive loading and also because, Stockum ('867) teaches that a curved edge improved releasability of the molded article.

In regard to claims 9 and 32-33, Jansen *et al.* ('113) do not teach a dip molding mandrel having a protruding portion away from the edge. Moe *et al.* ('331) teach a heart valve obtained by dip molding, said heart valve having polymer leaflets which exhibit an increased thickness at the edge (see col. 3, lines 50-60 and col. 6, lines 31-51). It is submitted that a dip mold used to make such a configuration includes a protruding portion away from the edge in order to increase the thickness of the edge, hence it is submitted that the dip mold (mandrel) of Moe *et al.* ('331) includes a protruding portion away from the edge. Therefore, it would have been obvious for one of ordinary skill in the art to have provided a protruding portion away from the edge as taught by

Art Unit: 1732

Moe *et al.* ('331) in the dip mold of Jansen *et al.* ('113) because, Moe *et al.* ('331) specifically teach that a thicker leaflet edge provides for an improved heart valve due to an increased strength to compressive loading. Furthermore, it is submitted that the actual dimension of the protruding portion, and hence of the groove, is a result-effective variable. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Therefore, it would have been obvious for one of ordinary skill in the art to have used routine experimentation to determine an groove dimension in the mandrel of Jansen *et al.* ('113) or NL 1008349 in view of Moe *et al.* ('331) because, Moe *et al.* ('331) specifically teach that a thicker leaflet edge provides for an improved heart valve due to an increased strength to compressive loading and also because a curved edge improves releasability of the molded article.

11. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen *et al.* (US Patent No. 5,376,113) or NL 1008349 in view of Henning *et al.* (US Patent No. 4,575,442).

Jansen *et al.* ('113) or NL 1008349 teaches the basic claimed mandrel as described above.

Regarding claim 35, Jansen *et al.* ('113) or NL 1008349 do not teach a coating the mandrel with a polymeric layer. Henning *et al.* ('442) teach providing a synthetic coating (polymeric) on a dip core (see col. 2, lines 15-22 and col. 3, lines 5-10). Therefore, it would have been obvious for one of ordinary skill in the art to have provided a synthetic coating (polymeric) on the dip mold in the mandrel of Jansen *et al.* ('113) or NL 1008349 because, Henning *et al.* ('442) teach that such a coating provides for an improved surface of the resulting molded product and also because all references teach similar materials, processes and end-products.

Art Unit: 1732

12. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce *et al.* (US Patent No. 4,364,127) in view of. Moe *et al.* (US Patent No. 6,174,331 B1).

Pierce *et al.* ('127) teach the basic claimed mandrel as described above.

Regarding claim 36, Pierce *et al.* ('127) do not teach a dip molding mandrel having a curved edge (radius of curvature). Moe *et al.* ('331) teach a heart valve obtained by dip molding, said heart valve having polymer leaflets which exhibit a radius of curvature and an increased thickness at the edge (see col. 3, lines 50-60; col. 6, lines 31-51 and Figure 6A).

Further, it should be noted that it is well known that in a dip molding process, as evidenced by Stockum ('867), a radius of curvature on the mandrel provides for improved releasability of the molded article (see Abstract). It should be noted that upon Applicants' request, the teachings of Stockum ('867) were employed to show that it is well known that in a dip molding process a radius of curvature on the mandrel provides for improved releasability of the molded article

Furthermore, it is submitted that a dip mold used to make such a configuration includes a radius of curvature in order to increase the thickness of the edge, hence it is submitted that the dip mold (mandrel) of Moe *et al.* ('331) includes an edge having a radius of curvature. Furthermore, it is submitted that the actual radius of curvature is a result-effective variable. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Therefore, it would have been obvious for one of ordinary skill in the art to have used routine experimentation to determine an optimum radius of curvature in the mandrel of Pierce *et al.* ('127) in view of Moe *et al.* ('331) and in further view of Stockum ('867), because Moe *et al.* ('331) specifically teach that a thicker leaflet edge provides for an improved heart valve due to an increased strength to compressive loading

Art Unit: 1732

and also because, Stockum ('867) teaches that a curved edge improves releasability of the molded article.

13. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce *et al.* (US Patent No. 4,364,127) in view of Henning *et al.* (US Patent No. 4,575,442).

Pierce *et al.* ('127) teach the basic claimed mandrel as described above.

Regarding claim 37, Pierce *et al.* ('127) do not teach a coating the mandrel with a polymeric layer. Henning *et al.* ('442) teach providing a synthetic coating (polymeric) on a dip core (see col. 2, lines 15-22 and col. 3, lines 5-10). Therefore, it would have been obvious for one of ordinary skill in the art to have provided a synthetic coating (polymeric) on the dip mold in the mandrel of Pierce *et al.* ('127) because, Henning *et al.* ('442) teach that such a coating provides for an improved surface of the resulting molded product and also because all references teach similar materials, processes and end-products.

Response to Arguments

14. Applicants' remarks filed September 18, 2002 (Paper No. 8) have been considered.

Applicants argue that in Jansen *et al.* ('113) "the free edge of the leaflets does not extend beyond the peak of feature (6)" and in Pierce *et al.* ('127) the "free edge of the leaflet (40) is along the middle of the top of shim 35" (see page 5-6 of the amendment filed September 18, 2002).

However, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26

Art Unit: 1732

USPQ2d 1057 (Fed. Cir. 1993). Specifically, as noted above, Jansen *et al.* ('113) teach a mandrel (7) having a plurality of ridges containing therebetween contoured surfaces (5) for forming polymer leaflets of a heart valve (valve prostheses) and further including an edge separating a top flat surface (8) from said contoured surfaces (5), said edge corresponding to free edges of said heart valve (valve prostheses) (see Figure 1). Furthermore, Pierce *et al.* ('127) Pierce *et al.* ('127) teach a top surface (40) formed by shims (35) that define an edge separating the contoured surfaces (see Figures 10 and 11), said edge being formed at the intersection of the leaflet, whereas the shim acts as an "edge" for the mandrel surface. It should be noted that whether a processing step is required to separate the leaflets is a mere functional aspect of using the mandrel and does not provide patentability to the mandrel.

Applicants argue that Moe *et al.* ('331) do not teach a "radius of curvature in order to increase the thickness of the edge" (see page 7 of the amendment filed September 18, 2002). However, as shown above, Moe *et al.* ('331) teach a heart valve obtained by dip molding, said heart valve having polymer leaflets which exhibit an increased thickness at the edge (see col. 3, lines 50-60 and col. 6, lines 31-51). It is submitted that in view of the teachings of Jansen *et al.* ('113) or NL 1008349 that teach a dip mold, whereas Moe *et al.* ('331) teach dip molding a thicker leaflet edge, it is submitted that a dip mold used to make such a configuration includes a protruding portion away from the edge in order to increase the thickness of the edge, hence it is submitted that the dip mold (mandrel) of Moe *et al.* ('331) includes a protruding portion away from the edge. It should be noted that, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or *motivation* to do so found either in the

Art Unit: 1732

references themselves *or in the knowledge generally available to one of ordinary skill in the art*. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992) (emphasis added).

Applicants request documentary support for the assertion that “it is well known that on a dip molding process a radius of curvature on the mandrel provides for improved releasability of the molded article” (see page 7 of the amendment filed September 18, 2002). As shown above, Stockum ('867) teaches that a radius of curvature on the mandrel provides for improved releasability of the molded article (see Abstract).

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1732

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stefan Staicovici, Ph.D. whose telephone number is (703) 305-0396. The examiner can normally be reached on Monday-Friday 8:00 AM to 5:30 PM and alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jan H. Silbaugh, can be reached at (703) 308-3829. The fax phone number for this Group is (703) 305-7718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Stefan Staicovici, PhD



AU 1732

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December 2, 2002